IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Watson, et al.	Docket No.:	2245.054
Serial No.:	10/543,014	Group Art Unit:	1626
Filed:	August 11, 2006	Examiner:	Sun Jae Y Loewe

Title: IMMUNOMODULATORY COMPOSITIONS

Confirmation No.: 4048

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Dear Sir:

I, Jonathon Mark TINSLEY, hereby state and declare that:

1. I am a citizen and resident of the United Kingdom;

2. I earned a BSc (hons) degree in Microbiology from the University of Leeds in 1981, a PhD degree in Cancer Studies from the University of Birmingham in 1991. My primary area of research, both academic and industrial has been in the area of anti-infectives and musculoskeletal diseases. I am presently Senior Director of Research & Development at Summit Corporation plc in Oxford, United Kingdom. Prior to my employment at Summit Corporation plc, I was Head of Biology at Oxagen, Oxford, United Kingdom and worked in the area of drug discovery therapeutics for asthma, rheumatoid arthritis and diabetes. Previous to that position I held a Senior Non-clinical fellowship with the Medical Research Council focusing on muscle disease based in Harwell, Oxfordshire.

3. I am the author of 50 articles and published abstracts in the area of anti-infectives and musculoskeletal disease.

4. In support of the enablement of the compounds claimed in the above application, I present herewith data from tests performed under my direct supervision (Exibit A).

5. Eight separate studies were conducted with the bacterium *Escherichia coli* (*E. coli*). The tests involved intraperitoneal challenge of C57BL6 mice with a single dose of 21,000 c.f.u./mouse at –24 hours with survival as endpoint. Test compounds were administered orally or by intraperitoneal injection at doses of between 0.01 and 100 mg/kg (sid and bid) at days –1 and –1 to +12. The results are summarized in Table 1 (Exhibit A).

6. Studies with the Ebola virus comprised two separate studies: (a) casuarine by intraperitoneal injection of single doses at 10 mg/kg and 100 mg/kg; (b) 3,7 diepicasuarine administered by intraperitoneal injection at a dose of 2 mg/kg (bid) at days –1 to +12. The tests involved intraperitoneal challenge of Balb/C mice (10 per group) with a single dose of 1,000 p.f.u./mouse at –24 hours with survival as endpoint. The results are summarized in Table 1 (Exhibit A).

7. The tularemia studies used the live vaccine strain (LVS) of the bacterium *Francisella tularensis* (the causative agent of tularemia), which is highly pathogenic in mice. The tests involved intraperitoneal challenge of C57BL6 mice (5 per group) with a single dose of 11,500 c.f.u./mouse at –24 hours with survival as endpoint as well as the intradermal challenge of C57BL6 mice (5 per group) with a single dose of 34,500 c.f.u./mouse at day 0, also with survival as endpoint. For the intraperitoneal challenge, test compounds were administered by intraperitoneal injection at doses of between 0.1 and 10 mg/kg (sid) at –24 hours. For the intradermal challenge, test compounds were administered orally at doses of between 0.2 and 2 mg/kg (sid) at days–1 to +12. . The results are summarized in Table 1 (Exhibit A).

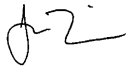
8. The anthrax studies used strain 34F2 (Sterne) of the bacterium *Bacillus anthracis* (the causative agent of anthrax). The tests involved intraperitoneal challenge of C57BL6 mice (2-8 per group) with a single dose of $9x10^7$ c.f.u./mouse at day 0 with survival as endpoint. Test compounds were administered by intraperitoneal injection at a dose of 10 mg/kg (sid) at –24

hours, and orally at doses of between 0.2 and 2 mg/kg (sid) at days−1 to +9. The results are summarized in Table 1 (Exhibit A).

9. As a person of skill in the art, I conclude that the experimental details and data referred to above indicate that the compounds claimed in the above application have antiviral and/or antibacterial activity.

10. I further declare that all statements of the foregoing declaration made of my own knowledge are true and that all statements made upon information and belief are believed true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issuing thereon.

Signed by me this 18th day of January, 2010.



Dr Jonathon Mark TINSLEY

Exhibit A

	Casuarine	3,7 diepicasuarine
E. Coli	40 - 75%	**40 – 80%**
Ebola	20% survival	**Not active**
Tularemia	20 - 40% survival	**60% Survival**
Anthrax	40-50% Survival	**40-50% Survival**